Code 33331 GIMAPLAY 1

1 CHANNEL ELECTROCARDIOGRAPH WITH GRAPHICAL DISPLAY AND PRINTER

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1. INTRODUCTION

Congratulations on your purchase of the new GIMAPLAY 1 electrocardiograph.
The GIMAPLAY 1 complies with the **Medical Devices Directive (93/42/EEC)** and therefore is labeled with the corresponding mark **CE 0068**.

2. CHARACTERISTICS AND SAFETY REFERENCES

GIMAPLAY 1 is a 1 channel electrocardiograph and is in class **II CF** according to the **EN60601-1** and **EN60601-2-25** norms.

FUNCTIONAL CHARACTERISTICS

1. LCD Display 128x64 dot
2. HIGH RESOLUTION THERMAL PRINTER (8 dots/mm). 1 channel hardcopy in real time with possibility to print the millimetric grid.
3. EASY PAPER LOADING.
4. Manual or Automatic RECORDING.
5. 5 seconds MEMORY for all 12 derivations.
6. DIGITAL FILTERS for elimination of muscles tremors, power line and base line disturbs.
7. Internal Ni-Cd Batteries with high capacity and fast charge time.
8. EASY OPERATION with one touch keys and menus.
9. Based on a RISC PROCESSOR for full digital signal processing.
10. REALLY PORTABLE. Small dimensions and light weight.

TECHNICAL CHARACTERISTICS

- POWER SUPPLY: Internal rechargeable Ni-Cd batteries
- LINE POWER SUPPLY: 220V~ ± 10%; 50 – 60Hz; 150 mA max; Isolation CL2 B
- BATTERY AUTONOMY: 3 hours
- APPLIED PART: CF type
- INPUT IMPEDANCE: > 100 Mohm
- FREQUENCY RESPONSE: 0,05 : 145Hz
- CMRR: > 100 dB TIME CONSTANT: > 3,2 s
- ACQUISITION: 12 bit 800 samples/sec/channel
- LEADS : 12 Standard
- SENSITIVITY: 5mm/mV; 10mm/mV; 20mm/mV ± 5%
- SCROLLING SPEED: 5mm/s; 10 mm/s; 25 mm/s; 50 mm/s
- SIGNAL MEMORY: 5s for each lead
- PRINTER: thermal printer 8dots/mm, paper 58 mm. – 60 mm.
- DISPLAY: LCD 128 x 64 dots
- FILTERS: muscles tremors 35Hz digital; power line interferences 50Hz 60Hz digital; high pass 0,5Hz digital
- DEFIBRILLATION PROTECTION: internal
- HARDCOPY: 1 channel
- DIMENSIONS: 190 x 120 x 60 mm.
- WEIGHT : 900 g. (with paper roll)
- CASE : IP 20
- OPERATION TEMPERATURE: +10°C ..... 40°C
- STORAGE TEMPERATURE: -10°C ..... 40°C
- RELATIVE OPERATIONAL UMIDITY: 25% ……95% without condensation
- CONFORMITY STANDARDS: 93/42/CEE; EN60601-1; EN60601-1-2 ; IEC601-2-25
- CLASSIFICATION : II a class (according to 93/42/CEE)
- SERIAL NUMBER : model symbol, year, month and progressive production

3. USE INSTRUCTIONS

3.1 INITIAL SET-UP AND AMBIENT CONDITIONS

GIMAPLAY 1 is built according to the CE standards and therefore is protected against electromagnetic interference from other devices. Nevertheless, in order to protect your device from other equipment that does not conform to the standards, it is recommended to:

- Avoid using cellular telephones in the vicinity especially during recording.
- Place the electrocardiograph as far as possible from electrical lines or static electricity sources to avoid the ECG signal disturbance.
- Avoid positioning of the electrocardiograph during recording, close to other diagnostic or therapeutic equipment like X-ray or ultrasound which can generate excessive electromagnetic interference.
- Perform the recording in a room with temperature between 20 and 25 degrees centigrade to avoid the patient feeling cold and induce the presence of muscle tremors.
- Do not expose the unit to excessive salty or humid environments.

3.2 RECOMMENDATIONS FOR SAFE USE

- Use the device in accordance with the instructions in this manual.
- The unit is delivered with a set of standard accessories. For reasons of safety, reliability and compatibility with the CE standards, use only the original accessories or others approved by the producer.
- GIMAPLAY 1 is equipped with thermal head printing mechanism which allows high quality hardcopy. To ensure the quality and reliability of the printer use only the original paper or one approved by the producer.
- Make sure that the line voltage corresponds to the voltage indicated on the batteries charger supplied with the unit.
- GIMAPLAY 1 has the isolation class **II CF** which means no ground connection is needed. Also the patient is fully isolated and defibrillation protected. The defibrillation protection is guaranteed only if the original patient cable is used.
- Check periodically the integrity of all accessories and the unit itself.
- Do not use the unit in presence of anesthetics or flammable gases.
- The producer is responsible for the unit in terms of safety, reliability and functionality only if:
    - The unit is used in accordance with the user instructions.
    - The electrical service at the location of use is according to the binding standards.
    - The repairs are performed by the producer or by an authorized service center.

- The unit is equipped with long life rechargeable batteries. However it is recommended to use only the original charger and to follow the procedures described in this manual to ensure the long autonomy of the batteries.

The producer is not responsible for damage to persons or the unit following the usage of a non-original charger.

3.3 POWER ON/OFF

To turn on/off the instrument press the main switch, placed on its back side. The initials screen will display the battery status bar.
If the charge value is lower than 75% please plug in the charger.
To start the work connect the patient cable, apply the electrodes on the patient and press any key**.**

3.4 KEY BOARD DESCRIPTION

(1) Paper Feed

(2) Sequential Mode or Printing Memory Data

(3) Manual Mode

(4) Isochronous (Automatic) Mode

(5) Paper Speed

(6) Sensitivity of Recording

(7) Anti Muscle Tremors Filter

(8) Anti Base Line Disturbs Filter

(9) Anti Power Line Disturbs Filter

(10/11) Vertical Arrows: Traces Group Selection
Modes Menu Selection

(12) Modes Menu

3.5 DEFAULT OPERATIONAL SET-UP

At power on the default set-up is:

- Traces Order: Standard
- Paper Speed: 25 mm/s
- Sensitivity of recording: 10 mm/mV
- Filters: Disabled
- Hardcopy frame length: 5 seconds

3.6 THE MAIN OPERATIONAL MODES

1. *Paper Speed:* 25mm/s at power on. Pushing the key (5) it is possible to select the paper speed: 50mm/s, 5mm/s, 10mm/s, 25mm/s…… 5mm/s ……..The mode appears on the display.

2. *Sensitivity of recording:* 10mm/mV by default. Pushing the key (6) it is possible to select the sensitivity of the trace: 20mm/mV, 5mm/mV…….10mm/mV…….The mode appears on the display.

3. *Filters*: disabled by default. Pushing the key (7), (8), (9) it is possible to enable the desired filter:

   - **LP**: anti muscle tremors filter
   - **HP**: anti base line disturbs filter
   - **N5/N6:** anti power line disturbs filter (N5 for 50 Hz and N6 for 60 Hz)

4. *Traces Group:* the Standard modality is predefined at power on and the display shows the I trace.
   It is possible to select the desired trace by pushing the keys (10) and (11).
   With the *Standard Modality* the display will show: I; II; III; aVr; aVL; aVF V_1; V_2; V_3; V_4; V_5; V_6
   Changing to *Cabrera modality*, the display will show: aVL; I; -aVR; II; aVF; III; V_1; V_2; V_3; V_4; V_5; V_6

3.7 THE MODES MENU

It is possible to select the Modes Menu pushing the key (12) and on the display will be shown:
- Mode: Standard
- Grid: off
- Table: on
- Frame: 5 sec.
- Exit

It is possible to change the mode by pushing the keys (10) (11) and the key (12) to confirm it. In order to continue the work with the new settings, select “Exit” and press the Menu key (12).

3.8 PREPARATION OF THE PATIENT

For a high quality ECG recording good preparation of the patient and correct positioning of the electrodes is necessary.

- The patient should be relaxed and the room temperature must be above 20 deg. centigrade to avoid the ecg signal to be disturbed by muscle tremors.
- Clean the skin where the electrodes will be placed with alcohol.
- Make sure that during recording the patient does not touch another person or conductive objects.

3.9 ELECTRODES APPLICATION

Apply a small quantity of conductive gel on the part of the skin where the electrodes will be placed (not necessary if disposable electrodes with pre-applied gel are used).

Position the electrodes according to the following scheme:

C1: on the 4^{th} intercostal space on the right parasternal part.
C2: on the 4^{th} intercostal space on the left parasternal part.
C3: on the 5^{th} rib, between C2 and C4.
C4: on the 5^{th} intercostal space, on the left hemiclavicular region.
C5: on the left anterior axillary, at the same level as C4.
C6: on the left mid-axillary at the level of C4.

Peripheral electrodes:

N: Right leg
R: Right hand
F: Left leg
L: Left hand

ECG DERIVATIONES ACCORDING TO IEC and AHA:

IEC	AHA
N Black	RL Green
R Red	RA White
C1 White/Red	V1 Brown/Red
C2 White/Yellow	V2 Brown/Yellow
C3 White/Green	V3 Brown/Green
C4 White/Brown	V4 Brown/Blue
C5 White/Black	V5 Brown/Orange
C6 White/Violet	V6 Brown/Violet
L Yellow	LA Black
F Green	LL Red

It is important not to use electrodes of different material as this can create polarization currents and disturb the base line of the ECG signals.

3.10 PRINTING TRACES

1. *Manual mode, in real time*: at any time, pressing the (3) "**Manual** key. To stop the print push again the same key.

2. *Isochronous mode **(suggested)***: pushing the key (4) the first leads group will be printed and in the same time the other leads are acquired and printed in sequence for 5 or 10 seconds according to the frame length set-up. After traces print, the message "MEMORY DATA" will be displayed. It is also possible to modify the parameters (paper speed, sensitivity of recording …..) and to reprint the traces in memory pushing the key "**Copy"** (2)**.** To exit this mode press again the key (4).

3. S*equential Mode:* pushing the key (2)**,** all the electrocardiograph leads are acquired and printed in real time. The print can be stopped by pressing the key (2) at any time.

3.11 LOADING THE THERMAL PAPER

When the thermal paper is finished, the "PAPER: ERROR*"* message appears on the display. Open the printer cover, insert the paper roll into the printer slot with the thermo sensible side down and finally close the printer cover.
Keep pushing the feed key (1) until the paper comes out of the printer straight.
The paper used – of high quality – can be diagrammed or white; in this case it is necessary to program the electrocardiograph for the Grid Print.

3.12 BATTERIES CHARGE

At the first utilization the batteries must be charged. During the first charge, it is suggested to turn off the instrument.
Connect the line power supply to the charge connector placed on the back side, near the main switch.
When the "*BATT: LOW"* message appears on the display it is necessary to recharge the batteries.
During charging a dynamic charge bar appears on the display, with the message "*Battery Charging"*.
At the charge end the charge bar will stop and the *"Charge Finished"* message will be shown, so it is possible to disconnect the charger.

ATTENTION: use only the original line power supply.

4. MAINTENANCE

4.1 GENERAL RECCOMENDATIONS

The equipment needs neither special servicing nor calibration.
For a correct maintenance, is recommended:

a. after use, clean the patient cables and the electrodes removing the gel residue
b. do not use aggressive chemical detergents, or vapour.
c. clean the unit with dry cotton.
d. the device cannot be sterilized. The electrodes can be sterilized with oxide of ethylene.
e. do not scratch the screen.
f. do not spill liquid on the unit.
g. do not pull patient cables.

4.2 PERIODIC CONTROLS

Periodically control the battery status bar. When the charge value is lower than 75%, please plug in the charger.

IMPORTANT

To insure a correct and long-lasting operation of the batteries it is necessary to control the charge status. If the device is not used, it is suggested to recharge the batteries every 2 weeks.

5. STANDARD ACCESSORIES

Carrying case (optional)
Consolle GIMAPLAY 1
Patient Cable
Electrodes Set
Power Cable
Paper roll
Gel Flacon
User Manual

6. TROUBLE SHOOTING

TROUBLES	CAUSES AND REMEDIES
Graphic not displayed	Batteries discharged
Faded hardcopy	Non original paper or batteries discharged
No hardcopy	Wrongly positioned paper roll, thermosensible side up.
Batteries not recharging	Verify power cable connection
Device does not turn on	Recharge the batteries
Faulty paper flow	End of paper roll, non original paper or wrongly positioned paper roll
Baseline drift	Dirty electrodes surface, insufficent skin contact or patient movement
Muscle tremors	Patient not relaxed; filter non active
Interferences on trace	Faulty patient cable; dirty electrodes surface or insufficent skin contact
Display turns off	Excessive electrical discharge. Switch off unit And wait 10/15 seconds then switch on